

PATENT  
USSN 09/843,676  
Docket 002943US; 018/181c

### REMARKS

This paper is responsive to the Office Action dated November 11, 2003 (Paper No. 11), which is the first action on the merits of the application.

Claims 21-32 were previously pending in the application. Claims 27, 28, 31, and 32 were withdrawn. The other claims were examined and stand variously rejected. Upon entry of this Amendment, certain claims are amended, and claims 33-40 are added. The added claims fall within the group under examination. Accordingly, claims 21-26, 29-30, and 33-40 are now pending in the application and under examination.

Further consideration and allowance of the application is respectfully requested.

### Interview Summary:

The undersigned wishes to express his gratitude to Examiner Malgorzata Walicka and Examiner Rebecca Prouty for the courtesy of a helpful and productive interview at the Patent Office on March 11, 2004. The rejections of record were discussed, and the undersigned proposed certain amendments to the claims. Suggestions made by the Examiners are incorporated into this response.

### Claim amendments:

Entry of the claim amendments does not introduce new matter into the disclosure. Support for the new claims may be found at various places in the specification, and the claims as previously presented. Production of polypeptides by recombinant expression or chemical synthesis (claims 33-34) is supported in the application as published (US 2002/0164786 A1) in paragraphs [0169], [0171] ff., and [0195]. Chimeric molecules comprising a telomerase peptide fused to another protein is supported in paragraphs [0206] and [0207].

Together, the claims under examination cover hTERT peptides of lengths from 5-10 amino acids of the native hTERT molecule (claims 29 or 38); or from 10 amino acids up to the full length of native hTERT (claims 21 or 35). The peptides may be present in the claimed product either alone, or part of a chimeric molecule that has one or more additional amino acids (claims 35 and 38). The peptides are optionally part of pharmaceutical or immunogenic compositions that may comprise other ingredients. The claimed compounds and compositions are now specified to have the capacity to induce hTERT specific antibody upon administration to a suitable subject. It will be recognized that

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small variations from the native hTERT sequence are equivalent to the structures explicitly indicated, providing that they have the functional property of being able to induce hTERT specific antibody.

Election of group for examination:

Applicants hereby confirm election of Group I (claims 21-26 and 29-30) for examination on the merits in this application, without traverse. New claims 33-40 also cover products containing hTERT peptides, and fall within Group I.

Objection to the Specification:

Applicants acknowledge the request from the Examiner for a substitute specification in accordance with 37 CFR § 1.125(a). A substitute specification is being provided to the Office in a separate submission.

Rejections under 35 USC § 112 ¶ 1:

The claims under examination stand rejected under the written description and enablement requirements of § 112 ¶ 1. The Office Action indicates that the specification does not describe all the peptides that would be useful falling within the claim, and that it would take undue experimentation to identify the functional species.

As indicated in the specification, a major utility of telomerase peptides is generating hTERT antibodies, which in turn may be useful as diagnostic aids, for telomerase purification, or for the benefit of the host. The claims have now been amended to indicate that each of the claimed products has the ability to induce anti-hTERT antibody.

Generating antibodies by administering peptide antigens to a suitable host is a broadly understood and easily implemented technology (paragraph [0208]). The skilled reader will recognize that a molecule as large of hTERT will have hundreds of immunogenic epitopes, and a short peptide of 5 to 9 amino acids can fill an antibody binding site. Of course, the user may use the entire hTERT molecule (either intact or fragmented) as an immunogen. But if they desire to use a fragment of the intact molecule, they can obtain immunogenic fragments either by prediction or by empirical testing.

Methods for determining immunogenic portions of protein antigens are well known in the art, and can be implemented without undue experimentation. For example, predictive methods are reviewed in Lu et al., Cancer Res. 60:5223, 2000; and Raddrizzani et al., Brief Bioinform. 1:179, 2000. Empirical methods and combinations are reviewed in Davenport et al., Immunogenetics 42:392,

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1995; Schirle et al., J. Immunol. Methods 257:1, 2001; and "Epitope Mapping Protocols", G. Morris ed., Humana Press. The skilled reader will know that once immunogenic epitopes are identified, an effective immunogenic composition can be made with a peptide or combination of peptides that comprise one or more of the many identified epitopes. Optionally, peptides can be conjugated to carriers such as KLH, or combined with an immunological adjuvant to enhance their immunogenicity (paragraphs [0206] and [0207]).

By request of the Examiners, the claims have been amended to indicate that the peptides "consist" of "5 to 10" or "10 or more" consecutive amino acids of the hTERT sequence (SEQ. ID NO:225). This provides coverage for immunogenic peptide compositions from about 5 amino acids up to the entire length of hTERT. New claims 35-40 explicitly indicate that the claimed peptides may have additional amino acids not in the hTERT sequence, providing that the combined sequence retains the property of being able to induce anti-hTERT antibody.

Withdrawal of these rejections is respectfully requested.

#### Double patenting

Certain claims in this application are provisionally rejected for obviousness type double patenting with respect to U.S. Patent 6,261,836.

Enclosed herewith is a Terminal Disclaimer with respect to the '836 patent.

Certain claims are provisionally rejected for obviousness type double patenting with respect to claim 1 of USSN 09/766,253 and 09/438,486.

Claim 1 has been canceled from USSN 09/766,253. The subject matter being prosecuted in that application is methods for detecting the presence of polynucleotide sequences.

Claim 1 has been canceled from USSN 09/438,486. The subject matter being prosecuted in that application is cDNA encoding hTERT.

Accordingly, there is no overlapping subject matter between the cited applications and the claims in the present application.

Certain claims are provisionally rejected for obviousness type double patenting with respect to certain claims of USSN 10/044,692. Applicants have not received a first Office Action in the 10/044,692 application. It is anticipated that the present application will be patented before the 10/044,692 application.

Withdrawal of these rejections is requested.

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Request for Rejoinder (MPEP § 821.04):

Claims 27-28 and 31-32 are method claims that depend from and incorporate the limitations of the product claims. Applicants hereby request that these claims be rejoined into the group under examination, upon determination that the product claims are patentable, in accordance with MPEP § 821.04.

Since the method claims incorporate the products and their structural limitations, no issues arise under 35 USC §§ 102 or 103. Furthermore, the product claims now all require that the products have the ability to induce anti-hTRT antibody. Accordingly, the products can be used to induce an anti-hTRT immunological response. Claims 27-28 and 31-32 can be rejoined into the case without raising extensive new issues.

Request for Interview

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicants hereby request an interview by telephone.

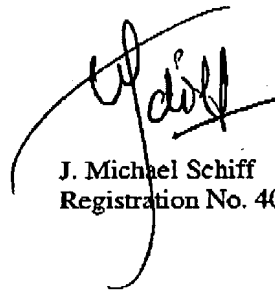
Fees Due

Enclosed with this Amendment is authorization to charge the Deposit Account for the new independent claims and the extension of time.

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Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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April 30, 2004



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